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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/775,691

02/10/2004

Michael M. Miller

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21837 7590 06/26/2008
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EXAMINER

RAMILLANO, LORE JANET

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

06/26/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/775,691	Applicant(s) MILLER, MICHAEL M.	
	Examiner LORE RAMILLANO	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/27/08.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 and 12-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. Applicant's reply filed on 3/27/08 is acknowledged. Claims 1-17 are pending. Claims 7-11 were amended. Claims 1-6 and 12-17 are withdrawn, and claims 7-11 are under examination.
2. This application contains claims 1-6 and 12-17 drawn to an invention nonelected without traverse in the reply filed on 10/11/07. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Response to Amendment

Claim Rejections - 35 USC § 112

3. The rejection of claims 7-11 are rejected under 35 U.S.C. 112, second paragraph, is maintained.

In the prior Office action (3/27/08), claim 7 was rejected because the claim language, "three distinct layers . . . , *in order* a) an adsorptive top layer . . . ; b) a reagent test pad . . . ; c) an interference removal pad," does not recite the subject matter which applicants regard as their invention (specification, p. 5, lines 1-7).

Applicant's amendment to claim 7 does not appear to resolve the basis of the rejection above because the order of the layers are not recited in the order recited in the specification, as cited above. Examiner recommends either deleting the claim language, "in order," or to amend the claim language to clarify that the reagent test pad is below the interference removal pad.

As stated in the prior Office action, for examination purposes, examiner will interpret that the reagent pad is located on the bottom layer, closest to the support element.

Prior art rejections

4. The rejections over the prior art are maintained.

Claim Rejections - 35 USC § 102

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. **Claims 7, 8, 10, and 11** are rejected under 35 U.S.C. 102(e) as being anticipated by Carroll et al. ("Carroll," US 6040195).

Carroll discloses a colorimetric testing device comprising a polymeric, non-reactive support element (figs. 3a-b, 13) with three distinct layers of varying lengths and an opening (i.e. figs. 3a-b, 18) through which the reagent test pad can be viewed, in order a) an adsorptive top layer (i.e. fig. 3a-b, 20) of a non-woven fabric which facilitates wetting of a plurality of layers below it; said layers prepared in varying lengths wherein each layer is longer than the one below it and each is independently attached to the

Art Unit: 1797

support element by adhesive; b) a reagent test pad (i.e. figs. 3a-b, 40) that comprises a small-porosity membrane c) an interference removal pad (i.e. figs. 3a-b, 30) that exhibits adsorptive properties towards anthocyanin-based substances in wine. (i.e. column 5, lines 15-50). The claimed “adsorptive properties towards anthocyanin-based substances in wine,” has been recited as a method of intended use and of no patentable moment with respect to the pending apparatus claim.

Carroll further discloses the following: the reagent test pad is comprised of materials selected from the group consisting of polysulfones, and filter paper (semi-porous membrane) (i.e. column 7, lines 19-39); the samples are tested for substances selected from the group consisting of pH, malic acid, lactic acid, residual yeast-fermentable sugar, acetaldehyde, acetic acid, ammonia, citric acid, hydrogen sulfide, potassium, alcohol, titratable acidity, harvest sugar, amino nitrogen, carbon dioxide, tannins and sulfur dioxide; and the sample is first deposited by droplets onto the top adsorptive layer, after which it proceeds to the next layer which is the interference removal pad whereby anthocyanin-based substances are trapped, after which it proceeds to the next layer which is the reagent test pad where colorimetric chemical reactions occur after a predetermined time period indicating the amount of lactic acid, malic acid, residual yeast-fermentable sugar, and pH of the sample.

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. **Claim 9** is rejected under 35 U.S.C. 103(a) as being unpatentable over Carroll in view of Carrico et al. ("Carrico," US 4806546).

Carroll does not specifically disclose having an interference pad consisting of polyamides and membranes produced from nylon.

Carrico discloses having amide groups in a nylon support for immobilizing nucleic acids such as DNA and RNA. Carrico further discloses that nucleic acids can be efficiently and stably immobilized on a solid support or matrix comprised of nylon having amide groups which have been derivatized to amidine residues (i.e. column 2, lines 3-46). It would have been obvious to a person of ordinary skill in the art to modify Carroll in view of Carrico by incorporating polyamides and membranes made from nylon into Carroll's interference pad because the combination of these elements enables more sensitive detection limits to be achieved (Carrico, column 2, lines 22-27).

Response to Arguments

8. Applicant's arguments filed 3/27/08 have been fully considered but they are not persuasive.

In response to applicant's argument that Carroll is designed to remove insoluble components (red blood cellular components) from the solution that is tested and the analyses of human blood and other fluids is not comparable to testing samples such as red wine, examiner does not find this argument convincing. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it

meets the claim. Here, in claim 7, the wine sample is not positively claimed in the body of the claim and is recited in the functional language. Because Carroll discloses the structural limitations recited in the claims, it is, therefore, capable of performing the colorimetric determination of a wine sample.

Applicant should note that claim 7 is not limited to the testing of wine samples since, as stated above, it is not positively recited in the body of the claim and is recited in the functional language.

In response to applicant's argument that Carroll's test strip has six layers, which perform different functions, examiner does not find this argument convincing. The transitional term, "comprising," is inclusive or open-ended and does not exclude additional, unrecited elements. Because applicant's claim includes this transitional term, applicant's test strip encompasses test strips with, i.e. more than four layers. With regard to the different functions of each layer, the function of Carroll's layers is of no patentable moment since claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function.

In response to applicant's argument that Carroll's test strip is not capable of not reacting with or removing anything from a sample, such as wine, examiner does not find this argument convincing. Products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Here, Carroll discloses the chemical composition of the test strip recited in claim 8. Therefore, because Carroll discloses a similar chemical composition, the properties applicant discloses and/or claims are necessarily present.

In response to applicant's argument that Carrico's nylon beads teaches away from their use as a means of removing non-specific interference contaminants like anthocyanins from an assay mixture by binding, examiner does not find applicant's argument convincing. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the prior Office action, examiner's reasoning to combine the references was based on knowledge which was within the level of ordinary skill in the art at the time of the claimed invention since the motivation to make detection devices more sensitive has been well known in the art for many years.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lore Ramillano whose telephone number is (571) 272-7420. The examiner can normally be reached on Mon. to Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-7420.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797

Lore Ramillano
Examiner
Art Unit 1797